REMARKS

The present communication responds to the Office Action of June 1, 2006. In that Office Action, the Examiner rejected each of the pending claims over various combinations of U.S. Patent 3,063,450 (Myerson et al.), US Patent 6,334,857 (Hollister et al.), and US Patent 6,719,737 (Kobayashi). Reconsideration and allowance of the claims is requested because none of the cited references, alone or in combination, disclose, teach, or suggest each element of the pending claims.

Objection to the drawings

The Examiner objected to the drawings under 37 CFR 1.83(a) saying that "they fail to show the protective cap 4 in figures 1 & 2 comprising a latching/connecting element as described in the specification." *Present Office Action, p. 2.*

The applicants note that Figure 1 illustrates a cannula support attached to an injection pen and comprising a non-fixedly latched protective cap and Figure 2 illustrates the arrangement shown in Figure 1, comprising a fixedly latched protective cap. The protective cap discussed in detail with reference to Figures 1 and 2 is protective cap 3. As discussed in the specification, the protective cap 3 has latching cams 1a, 1b, shown in Figures 1 and 2:

> The protective cap 3 comprises passages 3a in the lateral wall at its rear end, with which latching cams 1a, 1b of the cannula support 1 can engage. In the position of the protective cap 3 shown in FIG. 1, the cam 1b--smaller in comparison with the cam 1a--engages with the passage 3a and thus creates a weak latching connection, such that while the protective cap 3 is secured against unintentionally falling off of the cannula support 1, it can however be removed from the cannula support 1 by applying a small force for releasing the latching connection created by the small cam 1b. *US 2004/0111067, para. [0026].*

Element 4 illustrates a protective cap or packing sleeve 4 that may be plugged and/or screwed onto the protective cap 3:

> The outer protective cap or packing sleeve 4 shown in FIGS. 1 and 2 can optionally be plugged and/or screwed onto the protective cap 3, in order to protect the protective cap 3 and optionally the

> cannula support 1 or the front portion of the pen 5, for example from jolts or from forces acting from without. *US 2004/0111067, para. [0026]*.

The description of the outer protective cap 4 in Figures 1 and 2 is limited to the discussion reproduced above.

Figure 3 illustrates an embodiment wherein the outer protective cap 4 surrounds the inner protective cap 3 and comprises a left-handed thread 4a on its inner side, a corresponding counter thread 1d on the cannula support being screwed into the left-handed thread 4a, such that the outer protective cap 4 and the cannula support 1 are releasably connected to each other. *See US 2004/0111067, para. [0030]*. Figure 3 further illustrates cavities 4b on the outer protective sleeve 4 for receiving securing cams 1e of the cannula support. *See US 2004/0111067, para. [0030]*. Thus, Figures 3 and 4 illustrate embodiments wherein the outer protective cap 4 may be latched to the cannula support 1:

> Through this turning moment, for example, the securing cams 1e provided on the outer side of the cannula support 1 latch into corresponding cavities 4b of the outer protective cap 4, such that a fixed connection can be established between the outer protective cap 4 and the cannula support 1 ... The latching connection created by the latching elements 1e together with the cavities in the packing sleeve 4b prevents the cannula support 1 with the possibly used cannula 2 from being able to fall out of the outer protective cap 4, such that the danger of injury is reduced. *US 2004/0111067, para. [0033]*.
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> FIG. 4 shows the arrangement shown in FIG. 3, in a top view, wherein the latching elements 1e of the cannula support are in a position in which they latch with the corresponding cavities or recesses 4b in the outer protective cover 4, in order to prevent the cannula support 1 from falling out of the outer protective cover 4. *US 2004/0111067, para. [0034]*.

The applicants thus submit that all latching elements associated with the outer protective cap 4 are shown in the drawings as described in the specification.

37 CFR 1.83(a) requires: The drawing in a non-provisional application must show every feature of the invention specified in the claims. There is no requirement that every possible feature be shown in every drawing; merely that every feature specified in the claims be shown in

a drawing. No latching elements are described for the protective cap 4 in discussion of Figures 1 and 2. Accordingly, no latching elements are shown on the protective cap 4 in Figures 1 and 2. Latching elements are described on the cannula support to couple with recesses on the protective cap 4 in discussion of Figures 3 and 4. Accordingly, such latching elements and recesses are shown in Figures 3 and 4.

For the preceding reasons, the objection to the drawings should be withdrawn.

Rejection under 35 U.S.C. § 102

Claims 2, 4 & 8 were rejected under 35 U.S.C. § 102(b) as being anticipated by Myerson et al. This rejection is traversed at least for the following reason.

The Examiner asserts:

> The Myerson reference discloses a cannula system in figures 1-5 comprising a cannula support comprising a thread 38 turning in a first direction, an inner thread, and another thread 32 turning in a second, generally opposite direction, an outer thread; and a protective cap 12 having a thread engageable with said thread turning in said second generally opposite direction, and further comprising an injection device (18, 2, 4) having a thread 24 enageable with said thread 38 turning in the first direction. *Present Office Action, page 3.*

Myerson et al. teach a syringe that will permit the use of a needle that requires no attaching means attached to it. *Myerson et al., Col. 2, ll. 5-11.* More specifically, Myerson et al. teach a syringe with a chuck having jaw means for securely and releasably gripping the needle. *Myerson et al., Col. 2, ll. 28-30.*

The Examiner refers to a cannula support having a thread 38 turning in a first direction and another thread 32 turning in a second, generally opposite direction. Thread 38 is a threaded bore of a nut portion 16 and receives the lower end of a hollow tubular vise receiving tube 10; threads 32 are external threads of the lower end portion of the hollow tubular vise receiving tube 10:

> The lower end portion of the hollow tubular vise receiving tube 10 has external threads 32 and the upper end portion can be firmly secured to the nut portion 16 by a press fit between such upper portion and an aperture 34 in an end wall 36 of nut portion 16, in which aperture such upper portion of the tube 10 is received with the upper end thereof protruding into the threaded bore 38 of nut portion 16, as shown. *Myerson et al., Col. 3, ll. 62-69.*

Threads 38 cooperate to attach the chuck 6 to the syringe barrel 2:

> The chuck 6 is attached to the syringe barrel 2 by threading the nut portion 16 of the chuck over the threaded nipple fitting 18 as shown. *Myerson et al., Col. 3, ll. 59-61.*

Threads 32 cooperate to attach a screw cap 12:

> The bore of the screw cap 12 has a lower tapered portion 55 for cooperating with the external taper 56 of the jaws 11, and a threaded upper portion 57 for cooperating with the threads 32 of the tube 10 to move the screw cap axially over and with respect to the jaws 11 to tighten and loosen the jaws. The lower ends of the jaws 11 extend below the screw cap slightly when the jaws are closed by the cap. *Myerson et al., Col. 4, ll. 12-19.*

No discussion is given in Myerson et al. of the direction of the threads 38 and 32. Given that both sets of threads are intended for attaching the chuck to the syringe barrel (threads 38 doing so directly and threads 32 reinforcing such attachment), it is unlikely that they would have opposite directions. In any event, such opposite directions are not disclosed, taught, or suggested by the disclosure of Myerson et al. Thus, Myerson et al. do not, in fact, teach a cannula support comprising a thread turning in a first direction and a thread turning in a second, generally opposite direction.

Further, as may be appreciated from the above discussion, the screw cap of Myerson et al. is used to tighten and loosen the jaws of a tubular shaped hollow vise. Neither the screw cap nor the tubular shaped hollow vise cover the point of a needle. Referring to Figure 1 of Myerson et al., with the screw cap positioned on the jaws of the tubular shaped hollow vise, the needle extends distally of both the screw cap and the tubular shaped hollow vise and the point of the needle is exposed. Accordingly, Myerson et al. do not teach "a protective cap for covering a

point of a needle having a thread engageable with said thread turning in said second generally opposite direction," as recited by claim 4, as amended.

Accordingly, the applicants submit that claim 4 is not anticipated by Myerson et al. Each of claims 2 and 8 depend from claim 4 and thus are allowable for the reasons discussed with respect to claim 4. Reconsideration and allowance of claims 2, 4, and 8 over Myerson et al. are requested.

Claims 9-13 & 18 were rejected under 35 U.S.C. § 102(e) as being anticipated by Hollister et al. This rejection is traversed at least for the following reasons.

Hollister et al. teach a needle protection device having a collar and a housing flexibly attached thereto by means of a living hinge. *Hollister et al., Col. 3, ll. 7-10.* The protection device is pivotally connected:

> As noted above, once needle 12 is withdrawn from the patient after the medicament in vial 16 has been injected to the patient, to prevent the contaminated needle 12 from being further exposed to the environment, housing 6 is pivoted in the direction as indicated by arrow 14 to envelope needle 12. Needle 12 is secured within housing 6 by means of the interaction between hook 18 and needle 12, when hook 18 snaps over and retains needle 12 within housing 6. *Hollister, Col. 4, ll. 1-8.*

Thus, in Hollister et al., the housing of the needle protection device may be pivoted from a protecting position to an exposing position and vice versa.

The Examiner asserts:

> The Hollister reference discloses a cannula support in figure 2 comprising a protective cap 2 wherein at least one latching element, a recess seen in figure 2 with which element 7 cooperates, is provided on said cannula support and at least one corresponding latching element 7 is provided on said cap, the latching elements cooperating to create a latching connection between the cannula support and the protective cap 2. *Present Office Action, pp. 3-4.*

Elements 7 of the Hollister et al. needle protection device are hook tips that may engage the bottom surface of a hub:

> With specific reference to FIG. 2, note that to secure device 2 to vial 16, collar 4 is inserted about hub 10 of the needle assembly of vial 16 and pushed downward until hook tips 7 of collar 4 snap over the bottom surface 10a of hub 10. Since device 2 is made of a plastic material that has a given amount of flexibility and collar 4 is configured to fit closely to hub 10, when collar 4 is inserted about hub 10, its elasticity allows fingers 6 to expand until their respective hook tips snap over bottom surface 10a of hub 10. At which time fingers 6 will return to their natural configured state so that hook tips 7 are maintained behind bottom surface 10a to thereby fixedly coupled collar 4 to hub 10 of vial 16. Since collar 4 is coupled to hub 10 only due to the contact between hook tips 7 and the bottom surface 10a of hub 10, device 2 is rotatable about hub 10. *Hollister et al., Col. 3, ll. 32-46.*

Accordingly, the hook tips of Hollister et al. engage the device with the hub. There is no disclosure, teaching, or suggestion in Hollister et al. of latching elements cooperating to create a latching connection between a cannula support and a protective cap, "wherein the protective cap can be coupled to the cannula support in such a way that there is no connection between the latching elements and wherein a cannula is releasably covered when the protective cap is arranged on the cannula support with no connection between the latching elements and wherein a cannula is covered in a substantially non-releasable manner when the protective cap is arranged on the cannula support with a connection between the latching elements," as recited by claim 9, as amended. Similarly, there is no disclosure, teaching, or suggestion of a method for covering a cannula carried by a cannula support, "wherein the cannula is temporarily covered when the protecting cap is coupled to the cannula support but not to the latching element and permanently covered when the protecting cap is coupled to the latching element," as recited by claim 18.

The Examiner argues:

> With respect to claim 18, the reference discloses the method for covering a cannula carried by a cannula support using a cannula protecting cap, wherein the cannula support comprises a latching element 7 and wherein the cannula is temporarily covered when the protecting cap is coupled to the cannula support frictionally without the latching elements quite yet at the recess and permanently covered when the protecting cap is coupled to the latching element as seen in figure 2. *Present Office Action, p. 4.*

There is no support whatsoever for the Examiner's position. Specifically, there is no discussion in Hollister et al. of temporary frictional coupling. Nor is there any suggestion that there is a moment in time wherein the hook tips are not quite engaged with the hub and thus the cannula is temporarily covered. However, even if there was any support for the Examiner's position regarding frictional coupling, when the hook tips of Hollister et al. engage the device with the hub, the needle of Hollister et al. is not permanently covered. As shown in Figure 2, even after the hook tips of Hollister et al. engage the device with the hub, the needle may be exposed by pivoting the housing..

For at least the preceding reasons, Hollister et al. do not make obvious claims 9 or 18. Claims 10-13 depend from claim 9 and thus are allowable for the reasons discussed with respect to claim 9. Reconsideration and allowance of claims 9-13 and 18 over Hollister et al. are requested.

Rejection under 35 U.S.C. § 103

Claims 5-6 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Myerson et al. as applied by claim 4 and further in view of Hollister et al. This rejection is traversed at least for the following reasons.

As discussed above with respect to claim 4, Myerson et al. do not disclose, teach, or suggest, at least, "a cannula support comprising a thread turning in a first direction and another thread turning in a second, generally opposite direction" or "a protective cap for covering a point of a needle having a thread engageable with said thread turning in said second generally opposite direction," as recited by claim 4, as amended. Hollister et al. teach a needle protection device having a collar and a housing flexibly attached thereto by means of a living hinge. Hollister et al. do nothing to correct the fundamental teaching deficiencies of Myerson et al. with respect to claim 4. Accordingly, it is submitted that neither Myerson et al. or Hollister et al., alone or in combination, make obvious claim 4.

Claims 5 and 6 depend directly or indirectly from claim 4. Accordingly, claims 5 and 6 are allowable for the reasons discussed with respect to claim 4. Reconsideration and allowance of claims 5 and 6 over Myerson et al. in view of Hollister et al. are requested.

Claim 7 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Myerson et al. as applied to claim 4 and further in view of Hollister et al. as applied to claims 5-6 and further in view of Kobayashi. This rejection is traversed at least for the following reasons.

As discussed above with respect to the rejection of claims 5 and 6, neither Myerson et al. nor Hollister et al., alone or in combination, make obvious claim 4. The Examiner relies on Kobayashi to teach a second protective cap which is arranged with a protective cap. *Present Office Action, p. 6.* Kobayashi teaches a safety needle assembly having a removable protector positioned over a cannula and a sheath positioned over the protector. The sheath is pivotally connected such that it can be pivoted, after removal of the protector to expose the cannula, towards the cannula so that the cannulas passes through an opening in the sheath and is covered by the sheath. *Kobayashi, Abstract.*

Without addressing the Examiner's assertions regarding Kobayashi, Kobayashi does not correct the fundamental disclosure and teaching deficiencies of Myerson et al. and Hollister et al. with respect to claim 4. Claim 7 depends from claim 4. Accordingly, claim 7 is allowable for the reasons discussed with respect to claim 4. Reconsideration and allowance of claim 7 over Myerson et al. in view of Hollister et al. and further in view of Kobayashi are requested.

Claim 14 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Hollister et al. as applied to claim 9 and further in view of Kobayashi. This rejection is traversed at least for the following reasons.

The Examiner asserts that Kobayashi teaches the use of a circumferential ring 38 in figures 1 and 2, for providing a releasable connection with the cannula support and a cap with a corresponding element. Figure 2 illustrates the hub of a safety needle assembly. The hub assembly 20 includes a step 38:

> An annular recessed region 36 is positioned towards the distal side of the teeth 34 forming the first and second sets 30, 32 of projections. A step 38, 37 is thus formed on each axial end of the annular recessed region 36. That is, the portions 38, 37 of the hub 20 immediately adjoining the axial ends of the annular recessed region 36 each posses an outer diameter greater than the outer diameter of the annular recessed region 36.

The step is used to help orient the collar with respect to the cannula:

> There is thus an interest in properly orienting the collar 50 relative to the cannula, particularly the beveled end 42 of the cannula 40, to ensure that the sheath 80 is oriented in one of the two positions mentioned above relative to the bevel end 42 of the cannula 40. Thus, once the collar 50 is placed on the hub 20, it is necessary to be able to rotate the collar 50 to the desired relative position before the collar 50 is rotationally fixed on the hub the trough engagement of the teeth 34 on the outer surface of the hub 20 and the teeth 58 on the interior of the collar 50. For this reason, the inner diameter of the inwardly directed ridge 57 on the collar 50 possesses a diameter smaller than the outer diameter at the step 38 located at the distal side of the recessed region 36. With this relationship, when the collar 50 is placed on the hub 20 such as in the manner described above, the inwardly directed annular ridge 57 on the interior collar 50 contacts the end surface 38' of the step 38 shown in FIG. 2. The collar 50 is thus unable to move any further along the hub 20 in the absence of an additional applied force. However, the collar 50 is free to be rotated relative to the hub 20.

The step is thus used for mounting the collar on a hub; the collar, in turn, is used for mounting the sheath:

> The collar 50 is adapted to be mounted on the hub 20 by moving the collar 50 over the cannula 40 and into place on the hub 20 in the manner described in more detail below. In addition, the protector 70 is adapted to be moved over the cannula 40 and positioned in covering relation to the cannula 40 so that the cannula in enclosed within the protector 70. Further, as described in more detail below, the sheath 80 is adapted to be mounted on the collar 50 in a manner that allows the sheath 80 to be pivoted relative to the collar 50.

The Examiner asserts that the step of the hub for use in coupling of a collar to the hub comprises at least one second latching element provided on the cannula support that can engage with one of a corresponding counter element and the corresponding latching element on the protective cap to create a releasable connection between the cannula support and the protective cap. However, at best, the step of Kobayashi forms a latching element for coupling a collar and a hub. Neither the collar nor the hub comprise, at least, a protective cap.

Accordingly, neither Hollister et al. or Kobayashi disclose, teach, or suggest, "wherein at least one second latching element is provided on the cannula support and can engage with one of a corresponding counter element and the corresponding latching element on the protective cap to create a releasable connection between the cannula support and the protective cap," as recited by claim 14. Reconsideration and allowance of claim 14 are requested.

Claims 15-17 & 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hollister et al. as applied to claim 9 and further in view of Kobayashi as applied to claim 14 and further in view of Myerson et al.

As discussed above with respect to the rejection of claim 14, neither Hollister et al. or Kobayashi disclose, teach, or suggest, "wherein at least one second latching element is provided on the cannula support and can engage with one of a corresponding counter element and the corresponding latching element on the protective cap to create a releasable connection between the cannula support and the protective cap," as recited by claim 14. Each of claims 15-17 and 19 depend either directly or indirectly from claim 14.

Myerson et al. teach a syringe that will permit the use of a needle that requires no attaching means attached to it. *Myerson et al., Col. 2, ll. 5-11.* More specifically, Myerson et al. teach a syringe with a chuck having jaw means for securely and releasably gripping the needle. *Myerson et all, Col. 2, ll. 28-30.* Myerson et al. do not correct the fundamental teaching deficiencies of the combination of Hollister et al. and Kobayashi with respect to the rejection of claim 14.

Accordingly, it is submitted that none of Hollister et al., Kobayashi, or Myerson et al. disclose, teach, or suggest claim 14. As each of claims 15-17 and 19 depend either directly or indirectly from claim 14, they are allowable for the reasons discussed with respect to claim 14. Reconsideration and allowance are requested.

With respect to the rejection of claim 19, as previously discussed, Myerson et al. do not disclose, teach, or suggest a cannula support comprising a thread turning in a first direction and a thread turning in a second, generally opposite direction. Nor do Myerson et al. disclose, teach,

or suggest, a protective cap for covering a point of a needle having a thread engageable with said thread turning in said second generally opposite direction.

Claim 19 recites a "needle support comprising a cam and an inside surface with an inside thread for coupling the support to an injection device; an inner protective cap coupled to the needle support; and an outer protective cap generally surrounding the inner protective cap and comprising a left-handed thread and a cavity on an inside surface, said needle support comprising a complementary counter thread whereby the outer protective cap and the needle support may be releaseably connected to each other, said counter thread turning in a direction generally opposite to the inside thread". None of Myerson et al., Hollister et al., or Kobayashi disclose, teach, or suggest, at least, a needle support having an inside thread for coupling the support to an injection device, an outer protective cap comprising a left-handed thread, and a needle support comprising a complementary counter thread, said counter thread turning in a direction generally opposite to the inside thread.

Accordingly, reconsideration and allowance of claim 19 are requested.

Claims 20-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Myerson et al. as applied to claim 4 and further in view of Hollister et al. as applied to claim 9 and further in view of Kobayashi as applied to claim 14.

As can be appreciated from the discussion of the rejection of claims 20-26 as anticipated by Myerson et al., Myerson et al. do not disclose, teach, or suggest a cannula support comprising "a second portion having a second diameter greater than the first diameter, the second portion comprising an exterior thread turning in a first direction and an interior thread turning in a second, generally opposite direction," as recited by claim 20. Neither Hollister et al. or Kobayashi correct the fundamental teaching deficiencies of Myerson et al. with respect to claim 20.

Claims 21-26 depend either directly or indirectly from claim 20 and thus are allowable for the reasons discussed with respect thereto. Reconsideration and allowance of claims 20-26 are requested.

Conclusion

This paper does not generate any new claim fees, but a petition for an extension of time is submitted herewith, along with a check to cover the petition fee. The Commissioner is also hereby authorized to charge any deficiencies associated with this paper or the petition to Deposit Account No. 04-1420.

This application now stands in allowable form, and reconsideration and allowance are requested.

Respectfully submitted,

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Date: December 1, 2006

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